be completed within 3 to 4 months as compared to the 1 to 2 years typically required for indirect food additive petitions. The agency is concerned, however, that establishing a formal time limit for completion of such reviews will unduly restrict its ability to allocate its limited resources to projects that may be more critical. Therefore, the agency has decided not to establish a time limit for reviewing and responding to requests for exemptions from regulation as food additives at this time. As the agency gains experience with its threshold of regulation policy, it will consider establishing an appropriate time limit. In the interim, however, the agency is committed to reviewing exemption requests as expeditiously as resources allow.

27. One comment recommended that there be a phase-in process that would allow companies to carefully evaluate products that are on the market and to obtain exemption determinations where, and if, required.

As discussed previously, if the use of a substance results in, or is reasonably expected to result in, migration into food, even at low levels, and is not specifically excluded from the definition of a ''food additive'' in section 201(s) of the act, then the substance is a food additive that must either be the subject of a regulation authorizing its use or be exempted from regulation by FDA under the process specified in this rule. However, if the use of a substance in a food-contact article currently on the market involves low levels of migration into food (i.e., results in a dietary concentration at or below the threshold of regulatory concern), and is the subject of a request for an exemption under the process specified by this final rule, it is unlikely that FDA would take regulatory action during the time needed by the agency to complete its review. Therefore, the agency does not believe it is necessary to establish a phase-in program to allow companies to evaluate food-contact articles currently on the market.

28. One comment recommended that § 170.39 be revised to include an abbreviated review (i.e., one that does not require a review of environmental impact data and toxicological feeding study data) for those exemption requests that deal only with new uses of regulated indirect food additives that involve the same manufacturing process but a different technical effect (e.g., a substance currently regulated as a defoamer in the manufacture of paper and paperboard under § 176.170 that is the subject of an exemption request for its use as a deposit control agent in the manufacture of paper and paperboard).

The agency is currently reevaluating its environmental regulations under NEPA, and is committed to expanding the list of categorical exclusions found in § 25.24 (21 CFR 25.24). However, as indicated earlier, a key factor in FDA's decision to grant an exemption from regulation is whether the substance has a significant impact on the environment. A new use of a regulated indirect food additive that involves the same manufacturing process but a different technical effect may have, as a result of its use or subsequent disposal, a significantly different environmental exposure than any previously regulated use of the substance. Therefore, an abbreviated review (i.e., one that does not include a review of environmental impact data) is not justified for all such substances. Although these types of uses do not currently qualify for a categorical exclusion, some may qualify in the future (the categorical exclusion list is currently under consideration for expansion).

In regard to reducing the requirements for the submission of toxicological feeding studies, FDA emphasizes that § 170.39 requires only that submissions contain the results of an analysis of existing toxicological information on the substance and its impurities. This information is needed to show whether an animal carcinogen bioassay has been carried out, or whether there is some other basis for suspecting that the substance is a carcinogen or potent toxin. FDA also requires this type of information to enable it to determine whether any of the impurities present in the substance have been shown to be carcinogenic, and, if carcinogenic, whether their TD50 value is greater than 6.25 mg/kg bodyweight per day (see § 170.39(a)(1)). To clarify this issue, FDA is revising the language in § 170.39(c)(5) to state that the only toxicological information that must be included in a submission for an exemption from the food additive regulations is an analysis of existing toxicological information on the substance and its impurities.

29. Two comments stated that exempted substances should not be subjected to the environmental impact reviews typically required for food additives. The comments asserted that, instead, exempted substances should come under a newly created ''categorical exclusion'' that would exclude such actions from the requirement that an environmental assessment be prepared.

An FDA decision to exempt a substance from regulation as a food additive is an agency action under the National Environmental Policy Act (NEPA) (42 U.S.C. 4321). Under NEPA, an agency action must include a consideration of the environmental effects resulting from the intended use, unless it is the subject of one of the categorical exclusions listed in 21 CFR 25.24. Actions are made subject to an exclusion either because, as a class, they will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment, or because they meet specific criteria that are intended to ensure they will not cause significant environmental effects. As stated above, the agency is actively examining its categorical exclusion regulations. However, neither of the subject comments provided information to show that as a class, substances used in food-contact articles would not be introduced into the environment or to support the establishment of a new categorical exclusion. The agency welcomes the submission of data and information that would support the establishment of a categorical exclusion for these substances. At this time, however, all requests for threshold of regulation exemptions must include an abbreviated environmental assessment.

Availability of the Information Submitted

30. Six comments were submitted on the general subject of what types of information contained in submissions under § 170.39 should be made publicly available (i.e., on display at the Dockets Management Branch or released in response to requests submitted under the Freedom of Information Act (FOIA) (5 U.S.C. 552)). Three of these comments were quite general, recommending that FDA handle the confidential information contained in such submissions in the same manner that it has traditionally treated other documents submitted. A more specific comment recommended that the information released under FOIA should be consistent with that released from food additive petitions. One comment expressed the opposite viewpoint, stating that exempted substances should not be considered food additives, and that, therefore, the rules governing the release of information submitted on food additives should not apply. This comment also requested that the final regulation include a statement recognizing the possible trade secret status of information submitted in support of an exemption request. Another comment stated that the names of companies receiving exemption letters are trade secret.